A3356-3402

REDACTED

EXHIBIT 9

COMPARISON OF THE PRIOR ART WITH THE CLAIMS OF THE '7286 PATENT

Asserted Claim Limitation	Location in the Prior Art
1. A device comprising a metallic stent,	Applying either parties' proposed claim construction, the Berg patent discloses "***[a] device comprising a metallic stent***." For instance, Berg notes that the "the underlying structure of the stent can be virtually any stent design . . . whether metal or polymeric." (Berg patent, col. 3, ll. 29–32).
a biocompatible, nonabsorbable polymeric carrier, and	If the Court adopts Cordis's proposed construction of the term "biocompatible" (which, according to Cordis, simply requires that a polymeric material be "able to perform its function in the body with an acceptable biological response"), the Berg patent also discloses "***a biocompatible, nonabsorbable polymeric carrier.***" Berg notes that "[t]he polymer chosen must be a polymer that is biocompatible" and "[t]he polymer may be either a biostable or a bioabsorable polymer." (Berg patent at col. 4, ll. 35–42).[1]
a therapeutic agent,	The Berg patent discloses "***a therapeutic agent.***" In particular, Berg states that its "invention relates to intravascular stents for treatment of injuries to blood vessels and particularly to stents having a framework onto which a therapeutic substance or drug is applied." (Berg patent at col. 1, ll. 5–8; *see also* col. 5, ll. 19–39

[1] Furthermore, the Berg patent states, for example, that "polysaccharides" and "poly(ethylene- vingylacetate) [*sic*]" are deemed biocompatible polymers. (Berg patent at col. 4, l. 35–col. 5, l. 7). The specification of the '7286 patent further acknowledge that these polymers are biocompatible. (*See, e.g.*, '7286 patent, col. 6, ll. 43–49). In light of this, the Berg patent also discloses a "biocompatible, nonabsorbable polymeric carrier" under BSC's proposed construction of this term.

Asserted Claim Limitation	Location in the Prior Art
	(disclosing possible therapeutic agents for use on a stent)).
wherein: said polymeric carrier comprises an acrylate-based polymer or copolymer, a fluorinated polymer, or a mixture thereof, and	The Berg patent discloses the "***wherein: said polymeric carrier comprises an acrylate-based polymer or copolymer, a fluorinated polymer, or a mixture thereof***" limitation regardless of which parties' claim construction the Court adopts. Berg notes that "biostable polymers with a relatively low chronic tissue response [could be used] such as . . . polyvinylidene fluoride," a type of fluorinated polymer (Berg patent at col. 4, l. 54–62), and "acrylic polymers and copolymers" (*id.* at col. 4, l. 59; *see also id.* at col. 7, ll. 49–52), which are examples of an acrylate-based polymer or copolymer. Furthermore, Claim 6 of the Berg patent expressly recites several polymer classes from among the larger group disclosed in the patent, including both acrylate homopolymers and copolymers. (*Id.* at col. 7, ll. 49–53).
said therapeutic agent is rapamycin, or a macrocyclic lactone analog thereof, and	The Berg patent in combination with the Morris patent discloses "***rapamycin, or a macrocyclic lactone analog thereof.***" Specifically, the Berg patent teaches that "[t]he therapeutic substance used in the present invention could be virtually any therapeutic substance which possesses desirable therapeutic characteristics for application to a blood vessel. . . . . For example, . . . anti-inflammatory agents could be used." (Berg patent at col. 5, ll. 19–28). The Berg patent also discloses the use of a drug that "reduce[s] the amount of proliferation associated with arterial injury," (*id.* at col. 7, ll. 14–15) and that vascular smooth muscle cell proliferation causes restenosis (*id.* at col. 1, ll. 38–43). And the Morris patent discloses the use of rapamycin, a known anti-proliferative and anti-inflammatory agent, to inhibit vascular smooth muscle cell proliferation. For instance, the Morris patent claims, among other things, "administering an antirestenosis effective amount of rapamycin to said mammal . . .

Asserted Claim Limitation	Location in the Prior Art
	via a vascular stent impregnated with rapamycin." (Morris patent, Claim 1)
is present in an amount effective to inhibit neointimal proliferation.	The Berg patent discloses this limitation, which recites: "***and is present in an amount effective to inhibit neointimal proliferation.***" For instance, Berg notes that "[i]t is therefore an object of the present invention to provide a stent having a therapeutically significant amount of a drug applied thereto." (Berg patent, col. 2, ll. 13–15). Moreover, the Morris patent discloses specific *in vivo* dosing amounts for rapamycin when used to treat restenosis. (Morris patent, col. 6, ll. 39–64)
2. The device according to claim 1 wherein said therapeutic agent is a macrocyclic lactone analog of rapamycin.	The Skotnicki '286 patent discloses ***"macrocyclic lactone analog[s] of rapamycin"*** (under either parties' proposed claim construction) useful for the treatment of hyperproliferative vascular disease and restenosis as required by claims 2 and 4.[2] (*See* Skotnicki '286 patent, col. 1, ll. 64–66; col. 2, ll. 1–50; col. 5, l. 57–col. 6, l. 2). In addition to disclosing rapamycin analogs in general, the Skotnicki '286 patent discloses at least one particular rapamycin derivative (a macrocyclic lactone analog) that demonstrates superior activity to rapamycin in the disclosed thymocyte proliferation assay. (*See id.* at col. 8, ll. 43–col. 9, l. 2).
3. The device according to claim 1 that provides a controlled release of said therapeutic agent over a period of several weeks.	Claim 3 further adds the additional limitation: "***that provides a controlled release of said therapeutic agent over a period of several weeks.***" Under either parties' proposed construction the

[2] In fact, the Skotnicki '286 patent references Morris's work concerning the effect of rapamycin on smooth muscle cell proliferation and intimal thickening following vascular injury. (Skotnicki '286 patent, col. 1, ll. 43–46).

Asserted Claim Limitation	Location in the Prior Art
	Berg patent teaches this additional limitation: It is also an object of the present invention to provide a drug-containing stent which allows for sustained release of the drug to vascular tissue. (Berg patent at col. 2, ll. 21–23 (emphasis added)). Further, Berg notes that: The adhesion of the coating and the rate at which the drug is delivered can be controlled by the selection of an appropriate bioabsorbable or biostable polymer and by the ratio of drug to polymer in the solution. By this method, drugs such as . . . antiinflammatory agents can be applied to a stent, retained on a stent during expansion of the stent and elute the drug at a controlled rate. (*Id.* at col. 2, ll. 51–62 (emphasis added)). In addition to this general disclosure of controlled, sustained release, the Berg patent provides an example of a drug-eluting stent that elutes drug over a period of at least 10 days. (*See id.* at Fig. 1; col. 6, ll. 35–49). A person of ordinary skill in the art would understand that the Berg patent discloses how to formulate a polymer/drug mixture capable of eluting drug over a period of several weeks, and longer than the 10 days explicitly shown in Figure 1, by teaching that "[t]he release rate can be further controlled by varying the ratio of drug to polymer." (*Id.* at col. 2, ll. 62–63). Thus, it would have been obvious to a person of ordinary skill in the art – and well within that person's skill consistent with the specification's admission that such coating

Asserted Claim Limitation	Location in the Prior Art
	technology was "conventional" – to vary the ratio of drug to polymer to obtain a controlled release of drug over a period of two, three, or more weeks (i.e., "several weeks"). It was also well known that restenosis occurs over a period of several weeks, and therefore, it would have been reasonable for a person of ordinary skill in the art to develop a dosage form that would release drug from the stent over a period of several weeks. (*See, e.g.,* Morris patent, col. 6, ll. 57–60 (disclosing treatment with rapamycin for 14 days); *see also* Ex. 108 at BSC-SJA-1641 (In June 1994, long before the filing of the '662 patent, Dr. Lunn, another Cordis researcher, wrote "[d]esired features for [a stent] coating include . . . release in a time period of the order of 3 to 30 days"))
4. The device according to claim 2 that provides a controlled release of said therapeutic agent over a period of several weeks.	Claim 4 depends on claim 2 and further adds the additional limitation: "***that provides a controlled release of said therapeutic agent over a period of several weeks.***" *See* claim 3 for disclosure of this element in the prior art.
5. A method of inhibiting neointimal proliferation in a coronary artery resulting from percutaneous transluminal coronary angioplasty comprising implanting a device according to any one of claims 1 to 4 in the lumen of said coronary artery.	Claim 5 further adds the additional limitation: "***[a] method of inhibiting neointimal proliferation in a coronary artery resulting from percutaneous transluminal coronary angioplasty comprising implanting a device according to claims 1 to 4 in the lumen of said coronary artery.***" The Berg patent teaches this additional limitation of claim 5. Specifically, the Berg patent discloses a polymer-drug coated stent designed for implantation into a coronary artery to inhibit neointimal proliferation following percutaneous transluminal coronary angioplasty: This invention relates to intravascular stents for treatment of injuries to blood vessels and particularly to stents having a framework onto which a therapeutic

Asserted Claim Limitation	Location in the Prior Art
	substance or drug is applied. (Berg patent, col. 1, ll. 5–8 (emphasis added)). Further: In operation, the stent made according to the present invention can deliver drugs to a body lumen by introducing the stent transluminally into a selected portion of the body lumen and radially expanding the stent into contact with the body lumen. The transluminal delivery can be accomplished by a catheter designed for the delivery of stents and the radial expansion can be accomplished by balloon expansion of the stent, self-expansion of the stent, or a combination of self-expansion and balloon expansion. (*Id.* at col. 3, ll. 1–9).

EXHIBIT 10

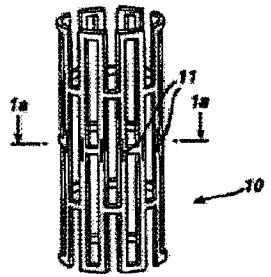
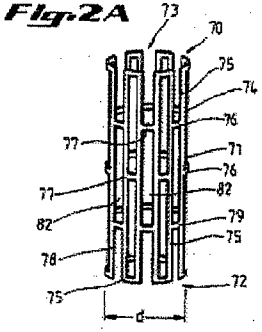
COMPARISON OF THE PRIOR ART WITH THE CLAIMS OF THE '3286 PATENT

Asserted Claim Limitation	Location in the Prior Art
1. A stent having a coating applied thereto,	Applying either parties' proposed claim construction, the Berg patent discloses ***"[a] stent having a coating applied thereto."*** Again, the Berg patent generally discloses a polymeric coated, drug-eluting stent. (Berg Patent, Abstract). Regarding the type of stent that can be used, Berg notes that the "the underlying structure of the stent can be virtually any stent design . . . whether metal or polymeric." (*Id.* at col. 3, ll. 29–32). And, as noted above, Berg discloses the application of a polymeric / drug coating to the stent itself. For instance, Berg describes "[t]he inclusion of a polymer in intimate contact with a drug on the stent allows the drug to be retained on the stent in a resilient matrix." (*Id.* at col. 2, ll. 36–38). And, Berg notes that "[i]n order to provide the coated stent according to the present invention, a solution which includes a solvent, a polymer dissolved in the solvent and a therapeutic substance dispersed in the solvent is first prepared . . . . The solution is applied to the stent and the solvent is allowed to evaporate, thereby leaving on the stent surface a coating of the polymer and the therapeutic substance." (*Id.* at col. 3, l. 52–col. 4, l. 21).
wherein said coating comprises a biocompatible polymer/drug mixture and	If the Court adopts Cordis's proposed construction of the term "biocompatible" (which, according to Cordis, simply requires that a polymeric material be "able to perform its function in the body with an acceptable biological response"), the Berg patent discloses the ***"said coating comprises a biocompatible polymer/drug mixture"*** limitation. Again, the Berg patent

Asserted Claim Limitation	Location in the Prior Art
	teaches "intravascular stents for treatment of injuries to blood vessels and particularly to stents having a framework onto which a therapeutic substance or drug is applied." (Berg patent at col. 1, ll. 5–8; *see also* col. 5, ll. 19–39 (disclosing possible therapeutic agents for use on a stent)). As noted above, Berg teaches the inclusion of the therapeutic substance or drug in a polymeric "matrix" (or alternatively stated, "[t]he inclusion of a polymer in intimate contact with a drug") which "allows the drug to be retained on the stent." (*Id.* at col. 2, ll. 36–38). Berg also notes that "[t]he polymer chosen must be a polymer that is biocompatible." (*Id.* at col. 4, ll. 35–42).[1]
said drug is rapamycin or a macrocyclic lactone analog thereof.	The Berg patent in combination with the Morris patent discloses ***"said drug is rapamycin or a macrocyclic lactone analog thereof."*** Specifically, the Berg patent teaches that "[t]he therapeutic substance used in the present invention could be virtually any therapeutic substance which possesses desirable therapeutic characteristics for application to a blood vessel. . . . . For example, . . . anti-inflammatory agents could be used." (Berg patent. at col. 5, ll. 19–28). The Berg patent also discloses the use of a drug that "reduce[s] the amount of proliferation associated with arterial injury," (*id.* at col. 7, ll. 14–15) and that vascular smooth muscle cell proliferation causes restenosis (*id.* at col. 1, ll. 38–43). And the Morris patent discloses the use of rapamycin, a known anti-proliferative and anti-inflammatory agent, to inhibit vascular smooth muscle cell proliferation. For instance, the

[1] Furthermore, the Berg patent states, for example, that "polysaccharides" and "poly(ethylene- vingylacetate) [*sic*]" are deemed biocompatible polymers. (Berg patent, col. 4, l. 35–col. 5, l. 7). The specification of the '3286 patent acknowledge that these polymers are biocompatible. (*See, e.g.*, '3286 patent, col. 6, ll. 34-47). In light of this, the Berg patent also discloses "biocompatible" polymeric materials under BSC's proposed construction of this term.

Asserted Claim Limitation	Location in the Prior Art
	Morris patent claims, among other things "administering an antirestenosis effective amount of rapamycin to said mammal . . . via a vascular stent impregnated with rapamycin." (Morris patent, Claim 1)
2. A stent according to claim 1 comprising a generally thin walled cylinder containing a plurality of generally solid struts to which said coating is applied.	Claim 2 additionally requires that the claimed stent comprise ***"a generally thin walled cylinder containing a plurality of generally solid struts to which said coating is applied."*** The Berg patent also discloses this additional limitation. Specifically, the Berg patent teaches that "the underlying structure of the stent can be virtually any stent design, whether of the self-expanding type or of the balloon-expandable type and whether metal or polymeric." (Berg patent, col. 3, ll. 29–32). Moreover, the Berg patent incorporates by reference the disclosure of U.S. Patent No. 4,733,665 (the "Palmaz patent"), and indicates the that the stent disclosed in the Palmaz patent can be used with the invention of the Berg patent. (*See id.* at col. 1, ll. 31–37, col. 3, ll. 32–36). The Palmaz patent discloses a stent that comprises a thin walled cylinder containing a plurality of generally solid struts. (*See* Palmaz patent, col. 7, ll. 3–28 ("tubular shaped member 71 is initially a thin-walled stainless steel tube, and the openings 82 between the intersecting bars 78 and 79 are formed by a conventional etching process, such as electromechanical or laser etching, whereby the resultant structure is a tubular shaped member 71 having a plurality of intersecting elongate members 78, 79"). Finally, the stent design illustrated in Figure 1 of the '3286 patent is identical to the stent design illustrated in Figure 2A of the Palmaz patent (but for the inclusion of channels 11 in Figure 1):

Asserted Claim Limitation	Location in the Prior Art
	FIG. 1  Fig-2A  (Compare '3286 patent, Fig. 1 with Palmaz patent, Fig. 2A). The Berg patent also discloses a coating that is applied to the stent structure. (*See* Berg patent, col. 2, ll. 40–44).
5. A stent according to claim 1 wherein the coating is dip-coated onto the stent.	Claim 5 additionally requires a stent where ***"the coating is dip-coated onto the stent."*** The Berg patent discloses that the coating can be dip-coated onto the stent by teaching that "the solution can be applied to the stent by . . . immersing the stent in the solution." (Berg patent at col. 4, ll. 22–24).
6. A stent according to claim 1 wherein the coating is spray-coated onto the stent.	Claim 6 additionally requires a stent where ***"the coating is spray-coated onto the stent."*** The Berg patent discloses a coating that can be sprayed onto the stent – "the solution can be applied to the stent by . . . spraying the solution onto the stent." (Berg patent at col. 4, ll. 22–23).
9. A stent according to claim 1 wherein the coating comprises a nonabsorbable polymer.	Claim 9 requires that the "coating" of claim 1 ***"comprises a nonabsorbable polymer."*** Applying either parties' proposed construction, the Berg patent discloses this additional limitation.

Asserted Claim Limitation	Location in the Prior Art
	Specifically, the Berg patent states that "[t]he polymer may be either a biostable or a bioabsorbable polymer." (Berg patent at col. 4, ll. 37–38 (emphasis added)). Berg also provides a list of suitable non-absorbable polymers – identified as "biostable" polymers by Berg – for use as stent coatings. (*See id.* at col. 4, l. 54–col. 5, l. 7).
10. A stent according to claim 1 wherein the coating comprises a lactone-based polyester; a lactone-based copolyester; a polyanhydride; a polyaminoacid; a polysaccharide; a polyphosphazene; a poly(ether-ester) copolymer; a polydimethylsiloxane; a poly(ethylene)vinylacetate; a poly(hydroxy)ethylmethylmethacrylate; an acrylate based polymer; an acrylate based copolymer; a polyvinyl pyrrolidone; a cellulose ester; a fluorinated polymer; or a blend thereof.	Claim 10 includes an additional limitation that requires the claimed stent's coating ***"comprise[] a lactone-based polyester; a lactone-based copolyester; a polyanhydride; a polyaminoacid; a polysaccharide; a polyphosphazene; a poly(ether-ester) copolymer; a polydimethylsiloxane; a poly(ethylene)vinylacetate; a poly(hydroxy)ethylmethylmethacrylate; an acrylate based polymer; an acrylate based copolymer; a polyvinyl pyrrolidone; a cellulose ester; a fluorinated polymer; or a blend thereof."*** The Berg patent discloses this additional limitation. Specifically, Berg references "polycaprolactone" (which is a lactone-based polyester), "polyanhydride," "poly(amino acids)," "cellulose" (which is a polysaccharide), "polyphosphazenes," "copoly(ether-esters) (*e.g.* PEO/PLA)" (which is a poly(ether-ester) copolymer), "ethylene-vinyl acetate copolymers" (which are poly(ethylene)vinylacetates), and "polyvinylidene fluoride" (which is a fluorinated polymer). (*See* Berg patent at col. 4, l. 43–col. 5, l. 7). The Berg patent also discloses that the coating can consist of "acrylate homopolymers and copolymers." (*Id.* at col. 7, l. 52).
21. A stent according to claim 10 wherein the coating comprises an acrylate based polymer.	Claim 21 requires that the claimed coating ***"comprise[ ] an acrylate based polymer."*** The Berg patent also discloses the additional limitation of claims 21 and 64 under either parties' proposed construction – specifically, the Berg patent discloses

Asserted Claim Limitation	Location in the Prior Art
	that the coating can consist of "acrylate homopolymers and copolymers." (Berg patent at col. 7, l. 52).
25. A stent according to claim 10 wherein the coating comprises a fluorinated polymer.	Claim 25 requires that the claimed coating ***"comprise[ ] a fluorinated polymer."*** Applying either parties' proposed construction, the Berg patent discloses this additional limitation by teaching the use of "polyvinylidene fluoride" (which is a fluorinated polymer). (*See* Berg patent at col. 4, l. 62).
27. A stent according to any one of claims 1 to 26 wherein said drug is a macrocyclic lactone analog of rapamycin.	The Skotnicki '286 patent complements the disclosure of the Morris patent, and discloses (under either parties' proposed claim construction) claim 27's additional limitation which requires that the drug be ***"macrocyclic lactone analog of rapamycin"*** useful for the treatment of hyperproliferative vascular disease and restenosis as required these dependent claims.[2] (*See* Skotnicki '286 patent, col. 1, ll. 64–66; col. 2, ll. 1–50; col. 5, l. 57–col. 6, l. 2). In addition to disclosing rapamycin analogs in general, the Skotnicki '286 patent discloses at least one particular rapamycin derivative (a macrocyclic lactone analog) that demonstrates superior activity to rapamycin in the disclosed thymocyte proliferation assay. (*See id.* at col. 8, ll. 43–col. 9, l. 2).
28. A stent according to any one of claims 1 to 26 that provides a controlled release of said rapamycin or macrocyclic lactone analog thereof over a period of several weeks.	Claim 28 require that the claimed stent ***"provides a controlled release of said rapamycin or macrocyclic lactone analog thereof over a period of several weeks."*** Under either parties' proposed construction, the Berg patent discloses the additional limitation present in dependent claims 28. The Berg patent teaches that: It is also an object of the present invention to

[2] In fact, the Skotnicki '286 patent references Morris's work concerning the effect of rapamycin on smooth muscle cell proliferation and intimal thickening following vascular injury. (Skotnicki '286 patent, col. 1, ll. 43–46).

Asserted Claim Limitation	Location in the Prior Art
	provide a drug-containing stent which allows for sustained release of the drug to vascular tissue. (*Id.* at col. 2, ll. 21–23 (emphasis added)). Further, Berg notes that: The adhesion of the coating and the rate at which the drug is delivered can be controlled by the selection of an appropriate bioabsorbable or biostable polymer and by the ratio of drug to polymer in the solution. By this method, drugs such as . . . antiinflammatory agents can be applied to a stent, retained on a stent during expansion of the stent and elute the drug at a controlled rate. (*Id.* at col. 2, ll. 51–62 (emphasis added)). In addition to this general disclosure of controlled, sustained release, the Berg patent provides an example of a drug-eluting stent that elutes drug over a period of at least 10 days. (*See id.* at Fig. 1; col. 6, ll. 35–49). A person of ordinary skill in the art would understand that the Berg patent discloses how to formulate a polymer/drug mixture capable of eluting drug over a period of several weeks, and longer than the 10 days explicitly shown in Figure 1, by teaching that "[t]he release rate can be further controlled by varying the ratio of drug to polymer." (*Id.* at col. 2, ll. 62–63). Thus, it would have been obvious to a person of ordinary skill in the art – and well within that person's skill consistent with the specification's admission that such coating technology was "conventional" – to vary the ratio of drug to polymer to obtain a controlled release of drug over a period of two, three, or more weeks (i.e., "several weeks"). It was also well known that restenosis occurs over a period of several weeks, and therefore, it would have been reasonable for a person of ordinary

Asserted Claim Limitation	Location in the Prior Art
	skill in the art to develop a dosage form that would release drug from the stent over a period of several weeks. (*See, e.g.*, Morris patent, col. 6, ll. 57–60 (disclosing treatment with rapamycin for 14 days); *see also* Ex. 108 at BSC-SJA-1641 (In June 1994, long before the filing of the '662 patent, Dr. Lunn, another Cordis researcher, wrote "[d]esired features for [a stent] coating include . . . release in a time period of the order of 3 to 30 days")).
29. A stent according to claim 28 wherein said drug is a macrocyclic lactone analog of rapamycin.	The Skotnicki '286 patent discloses the additional limitation of claim 29 (***"wherein said drug is a macrocyclic lactone analog of rapamycin"***) for the same reasons discussed in connection with claim 27.
30. A stent according to any one of claims 1 to 26 that releases said rapamycin or macrocyclic lactone analog thereof over a period of at least 14 days.	Claim 30 requires that the claimed stent ***"release[ ] said rapamycin or macrocyclic lactone analog thereof over a period of at least 14 days."*** For the same reasons discussed above in connection with dependent claims 28, the Berg patent discloses all the limitations of claim 30.
31. A stent according to claim 30 wherein said drug is a macrocyclic lactone analog of rapamycin.	The Skotnicki '286 patent discloses the additional limitation of claim 31 (***"wherein said drug is a macrocyclic lactone analog of rapamycin"***) for the same reasons discussed in connection with claim 27.
32. A stent according to any one of claims 1 to 26 wherein said rapamycin or macrocyclic lactone analog thereof is present in a therapeutically beneficial amount to inhibit neointimal proliferation.	Claim 32 additionally requires: ***"wherein said rapamycin or macrocyclic lactone analog thereof is present in a therapeutically beneficial amount to inhibit neointimal proliferation."*** Applying either parties' claim construction, the Berg patent also discloses the additional limitation of claim 32. For instance, Berg notes that "[i]t is therefore an object of the present invention to provide a stent having a therapeutically significant amount of a drug applied thereto." (Berg patent, col.

Asserted Claim Limitation	Location in the Prior Art
	2, ll. 13–15). Moreover, the Morris patent discloses specific *in vivo* dosing amounts for rapamycin when used to treat restenosis. (Morris patent, col. 6, ll. 39–64).
33. A stent according to claim 32 wherein said drug is a macrocyclic lactone analog of rapamycin.	The Skotnicki '286 patent discloses the additional limitation of claim 33 (***"wherein said drug is a macrocyclic lactone analog of rapamycin"***) for the same reasons discussed in connection with claim 27.
34. A stent according to claim 33 that releases said macrocyclic lactone analog of rapamycin over a period of at least 14 days.	The Berg patent discloses the additional limitation of claim 34 (***"releases said macrocyclic lactone analog of rapamycin over a period of at least 14 days"***) for the same reasons discussed in connection with claim 30.
35. A stent according to claim 34 wherein the coating comprises a fluorinated polymer.	The Berg patent discloses the additional limitation of claim 35 (***"wherein the coating comprises a fluorinated polymer"***) for the same reasons discussed in connection with claim 25.
36. A stent according to claim 35 wherein the coating further comprises an acrylate based polymer or copolymer.	The Berg patent discloses the additional limitation of claim 36 (***"wherein the coating further comprises an acrylate based polymer or copolymer"***) for the same reasons discussed in connection with claim 21.
37. A stent according to claim 33 that provides a controlled release of said rapamycin or macrocyclic lactone analog thereof over a period of several weeks.	The Berg patent discloses the additional limitation of claim 37 (***"provides a controlled release of said rapamycin or macrocyclic lactone analog thereof over a period of several weeks"***) for the same reasons discussed in connection with claim 28.
38. A stent according to claim 37 wherein the coating comprises a fluorinated polymer.	The Berg patent discloses the additional limitation of claim 38 (***"wherein the coating comprises a fluorinated polymer"***) for the same reasons discussed in connection with claim 25.

Asserted Claim Limitation	Location in the Prior Art
39. A stent according to claim 38 wherein the coating further comprises an acrylate based polymer or copolymer.	The Berg patent discloses the additional limitation of claim 39 (***"wherein the coating further comprises an acrylate based polymer or copolymer"***) for the same reasons discussed in connection with claim 21.
40. A device comprising a metallic stent,	Applying either parties' proposed claim construction, the Berg patent discloses ***"[a] device comprising a metallic stent"*** for the same reasons discussed above in connection with claim 1's ***"[a] stent having a coating applied thereto"*** limitation.
a biocompatible polymeric carrier and a drug,	The Berg patent discloses the ***"a biocompatible polymeric carrier and a drug"*** limitation of claim 40 for the same reasons discussed in connection with the ***"said coating comprises a biocompatible polymer/drug mixture"*** limitation of claim 1.
wherein said drug is rapamycin or a macrocyclic lactone analog thereof and	The Berg patent in combination with the Morris patent discloses the ***"wherein said drug is rapamycin or a macrocyclic lactone analog thereof"*** limitation of claim 40 for the same reasons described in connection with the ***"said drug is rapamycin or a macrocyclic lactone analog thereof"*** limitation of claim 1.
is present in an amount effective to inhibit neointimal proliferation.	The Berg patent discloses this limitation, which requires that the drug be ***"present in an amount effective to inhibit neointimal proliferation."*** For instance, Berg notes that "[i]t is therefore an object of the present invention to provide a stent having a therapeutically significant amount of a drug applied thereto." (Berg patent, col. 2, ll. 13–15). Moreover, the Morris patent discloses specific *in vivo* dosing amounts for rapamycin when used to treat restenosis. (Morris patent, col. 6, ll. 39–64).
41. A device according to claim 40 wherein said polymeric carrier	Claim 41 requires that: ***"said polymeric carrier and drug are***

Asserted Claim Limitation	Location in the Prior Art
and drug are mixed together.	***mixed together."*** The Berg patent discloses this additional limitation of claim 41. Berg states that the coating is prepared using "a solution which includes a solvent, a polymer dissolved in the solvent and a therapeutic substance dispersed in the solvent . . . . The solution is applied to the stent and the solvent is allowed to evaporate, thereby leaving on the stent surface a coating of the polymer and the therapeutic substance." (Berg patent, col. 3, l. 53–col. 4, l. 21). Moreover, "[t]he inclusion of a polymer in intimate contact with a drug on the stent allows the drug to be retained in a resilient matrix during expansion of the stent and also slows the administration of drug following implantation." (*Id.* at col. 2, ll. 36–40).
44. A device according to claim 40 wherein said stent comprises a generally thin walled cylinder containing a plurality of generally solid struts to which said polymeric carrier and drug are applied.	The Berg patent discloses the additional limitation of claim 44 (***"wherein said stent comprises a generally thin walled cylinder containing a plurality of generally solid struts to which said polymeric carrier and drug are applied."*** for the same reasons discussed above in connection with claim 2.
47. A device according to claim 40 wherein the polymeric carrier and drug are dip-coated onto the stent.	The Berg patent discloses the additional limitation of claim 47 (***"wherein the polymeric carrier and drug are dip-coated onto the stent"***) for the same reasons discussed above in connection with claim 5.
48. A device according to claim 40 wherein the polymeric carrier and drug are spray-coated onto the stent.	The Berg patent discloses the additional limitation of claim 48 (***"wherein the polymeric carrier and drug are spray-coated onto the stent"***) for the same reasons discussed in connection with claim 6.
51. A device according to claim 40 wherein the polymeric carrier comprises a nonabsorbable polymer.	The Berg patent discloses the additional limitation of claim 51 (***"comprises a nonabsorbable polymer"***) for the same reasons described in connection with the ***"comprises a nonabsorbable***

Asserted Claim Limitation	Location in the Prior Art
	polymer" limitation of claim 9.
52. A device according to claim 40 wherein the polymeric carrier comprises a lactone-based polyester; a lactone-based copolyester; a polyanhydride; a polyaminoacid; a polysaccharide; a polyphosphazene; a poly(ether-ester) copolymer; a polydimethylsiloxane; a poly(ethylene)vinylacetate; a poly(hydroxy)ethylmethylmethacrylate; an acrylate based polymer; an acrylate based copolymer; a polyvinyl pyrrolidone; a cellulose ester; a fluorinated polymer; or a blend thereof.	The Berg patent discloses the additional limitation of claim 52 (which requires that the polymeric carrier ***"comprise[] a lactone-based polyester; a lactone-based copolyester; a polyanhydride; a polyaminoacid; a polysaccharide; a polyphosphazene; a poly(ether-ester) copolymer; a polydimethylsiloxane; a poly(ethylene)vinylacetate; a poly(hydroxy)ethylmethylmethacrylate; an acrylate based polymer; an acrylate based copolymer; a polyvinyl pyrrolidone; a cellulose ester; a fluorinated polymer; or a blend thereof"***) for the same reasons discussed above in connection with the additional limitation of claim 10.
63. A device according to claim 52 wherein the polymeric carrier comprises an acrylate based polymer.	The Berg patent discloses the additional limitation of claim 63 (which requires that the polymeric carrier ***"comprise[ ] an acrylate based polymer"***) for the same reasons discussed above in connection with the additional limitation of claim 21.
67. A device according to claim 52 wherein the polymeric carrier comprises a fluorinated polymer.	The Berg patent discloses the additional limitation of claim 67 (which requires that the polymeric carrier ***"comprise[ ] a fluorinated polymer"***) for the same reasons discussed above in connection with claim 25.
69. A device according to any one of claims 40 to 68 wherein said drug is a macrocyclic lactone analog of rapamycin.	The Skotnicki '286 patent discloses the additional limitation of claim 69 (***"wherein said drug is a macrocyclic lactone analog of rapamycin"***) for the same reasons discussed in connection with claim 27.
70. A device according to any one of claims 40 to 68 that provides a controlled release of said rapamycin or macrocyclic	The Berg patent discloses the additional limitation of claim 70 (which requires that the claimed stent ***"provides a controlled release of said rapamycin or macrocyclic lactone analog thereof***

Asserted Claim Limitation	Location in the Prior Art
lactone analog thereof over a period of several weeks.	***over a period of several weeks"***) for the same reasons discussed in connection with the additional limitation of claim 28.
71. A device according to claim 70 wherein said drug is a macrocyclic lactone analog of rapamycin.	The Skotnicki '286 patent discloses the additional limitation of claim 71 (***"wherein said drug is a macrocyclic lactone analog of rapamycin"***) for the same reasons discussed in connection with claim 27.
72. A device according to claim 71 wherein the polymeric carrier comprises a fluorinated polymer.	The Berg patent discloses the additional limitation of claim 72 (***"wherein the polymeric carrier comprises a fluorinated polymer"***) for the same reasons discussed in connection with claim 25.
73. A device according to claim 72 wherein the polymeric carrier further comprises an acrylate based polymer or copolymer.	The Berg patent discloses the additional limitation of claim 73 (***"wherein the polymeric carrier further comprises an acrylate based polymer or copolymer"***) for the same reasons discussed in connection with claim 21.
74. A device according to any one of claims 40 to 68 that releases said drug over a period of at least 14 days.	The Berg patent discloses the additional limitation of claim 74 (***"release[ ] said rapamycin or macrocyclic lactone analog thereof over a period of at least 14 days"***) for the same reasons described in connection with claim 30.
75. A device according to claim 74 wherein said drug is a macrocyclic lactone analog of rapamycin.	The Skotnicki '286 patent discloses the additional limitation of claim 75 (***"wherein said drug is a macrocyclic lactone analog of rapamycin"***) for the same reasons discussed in connection with claim 27.
76. A device according to claim 75 wherein the polymeric carrier comprises a fluorinated polymer.	The Berg patent discloses the additional limitation of claim 76 (***"wherein the polymeric carrier comprises a fluorinated polymer"***) for the same reasons discussed in connection with claim 25.

Asserted Claim Limitation	Location in the Prior Art
77. A device according to claim 76 wherein the polymeric carrier further comprises an acrylate based polymer or copolymer.	The Berg patent discloses the additional limitation of claim 77 (***"wherein the polymeric carrier further comprises an acrylate based polymer or copolymer"***) for the same reasons discussed in connection with claim 21.

EXHIBIT 11

COMPARISON OF THE PRIOR ART WITH THE CLAIMS OF THE '473 PATENT

Asserted Claim Limitation	Location in the Prior Art
1. A metallic stent having a coating applied thereto, wherein:	Applying either parties' proposed claim construction, the Berg patent discloses "***[a] metallic stent having a coating applied thereto***." For instance, Berg notes that the "the underlying structure of the stent can be virtually any stent design . . . whether metal or polymeric." (Berg patent, col. 3, ll. 29–32). And, as noted above, Berg discloses the application of a polymeric / drug coating to the stent itself. For instance, Berg describes "[t]he inclusion of a polymer in intimate contact with a drug on the stent allows the drug to be retained on the stent in a resilient matrix." (*Id.* at col. 2, ll. 36–38). And, Berg notes that "[i]n order to provide the coated stent according to the present invention, a solution which includes a solvent, a polymer dissolved in the solvent and a therapeutic substance dispersed in the solvent is first prepared . . . . The solution is applied to the stent and the solvent is allowed to evaporate, thereby leaving on the stent surface a coating of the polymer and the therapeutic substance." (*Id.* at col. 3, l. 52–col. 4, l. 21).
said coating comprises a mixture of a biocompatible polymeric carrier and a therapeutic agent;	If the Court adopts Cordis's proposed construction of the term "biocompatible" (which, according to Cordis, simply requires that a polymeric material be "able to perform its function in the body with an acceptable biological response"), the Berg patent also discloses "***said coating comprises a mixture of a biocompatible polymeric carrier and a therapeutic agent.***" Again, the Berg patent teaches "intravascular stents for treatment of injuries to blood vessels and particularly to stents having a framework onto

Asserted Claim Limitation	Location in the Prior Art
	which a therapeutic substance or drug is applied." (Berg patent at col. 1, ll. 5–8; *see also* col. 5, ll. 19–39 (disclosing possible therapeutic agents for use on a stent)). As noted above, Berg teaches the inclusion of the therapeutic substance or drug in a polymeric "matrix" (or alternatively stated, "[t]he inclusion of a polymer in intimate contact with a drug"). (*Id.* at col. 2, ll. 36–38). Berg also notes that "[t]he polymer chosen must be a polymer that is biocompatible." (*Id.* at col. 4, ll. 35–42). [1]
said polymeric carrier comprises at least one nonabsorbable polymer;	The Berg patent also discloses ***"said polymeric carrier comprises at least one nonabsorbable polymer,"*** regardless of which parties' claim construction the Court adopts. For example, Berg notes that "[t]he polymer may be either a biostable or a bioabsorable polymer." (Berg patent at col. 4, ll. 35–42).
said therapeutic agent is rapamycin, or a macrocyclic lactone analog thereof,	The Berg patent in combination with the Morris patent discloses (again, under either parties' claim construction), this limitation which recites: ***"said therapeutic agent is rapamycin, or a macrocyclic lactone analog thereof."*** Specifically, the Berg patent teaches that "[t]he therapeutic substance used in the present invention could be virtually any therapeutic substance which possesses desirable therapeutic characteristics for application to a blood vessel. . . . . For example, . . . anti-inflammatory agents could be used." (Berg patent at col. 5, ll. 19–28). The Berg patent also discloses the use of a drug that "reduce[s] the amount of proliferation associated with arterial injury," (*id.* at col. 7, ll.

[1] Furthermore, the Berg patent states, for example, that "polysaccharides" and "poly(ethylene- vingylacetate) [*sic*]" are deemed biocompatible polymers. (Berg patent, col. 4, l. 35–col. 5, l. 7). The specification of the '473 patent acknowledge that these polymers are biocompatible. (*See, e.g.*, '473 patent, col. 6, ll. 38–50). In light of this, the Berg patent also discloses a "biocompatible polymeric carrier" under BSC's proposed construction of this term.

Asserted Claim Limitation	Location in the Prior Art
	14–15) and that vascular smooth muscle cell proliferation causes restenosis (*id.* at col. 1, ll. 38–43). And the Morris patent discloses the use of rapamycin, a known anti-proliferative and anti-inflammatory agent, to inhibit vascular smooth muscle cell proliferation. For instance, the Morris patent claims, among other things, "administering an antirestenosis effective amount of rapamycin to said mammal . . . via a vascular stent impregnated with rapamycin." (Morris patent, Claim 1).
present in an amount effective to inhibit neointimal proliferation; and	The Berg patent discloses this limitation, which requires that the therapeutic agent be ***"present in an amount effective to inhibit neointimal proliferation."*** For instance, Berg notes that "[i]t is therefore an object of the present invention to provide a stent having a therapeutically significant amount of a drug applied thereto." (Berg patent, col. 2, ll. 13–15). Moreover, the Morris patent discloses specific *in vivo* dosing amounts for rapamycin when used to treat restenosis. (Morris patent, col. 6, ll. 39–64).
said stent provides a controlled release of said therapeutic agent over a period of several weeks.	The final limitation of claim 1 of the '473 patent, requires that ***"said stent provides a controlled release of said therapeutic agent over a period of several weeks."*** Under either parties' proposed construction the Berg patent teaches this limitation: It is also an object of the present invention to provide a drug-containing stent which allows for sustained release of the drug to vascular tissue. (Berg patent at col. 2, ll. 21–23 (emphasis added)). Further, Berg notes that: The adhesion of the coating and the rate at which the drug is delivered can be controlled by the selection of an appropriate bioabsorbable or

Asserted Claim Limitation	Location in the Prior Art
	biostable polymer and by the ratio of drug to polymer in the solution. By this method, drugs such as . . . antiinflammatory agents can be applied to a stent, retained on a stent during expansion of the stent and elute the drug at a controlled rate. (*Id.* at col. 2, ll. 51–62 (emphasis added)). In addition to this general disclosure of controlled, sustained release, the Berg patent provides an example of a drug-eluting stent that elutes drug over a period of at least 10 days. (*See id.* at Fig. 1; col. 6, ll. 35–49). A person of ordinary skill in the art would understand that the Berg patent discloses how to formulate a polymer/drug mixture capable of eluting drug over a period of several weeks, and longer than the 10 days explicitly shown in Figure 1, by teaching that "[t]he release rate can be further controlled by varying the ratio of drug to polymer." (*Id.* at col. 2, ll. 62–63). Thus, it would have been obvious to a person of ordinary skill in the art – and well within that person's skill consistent with the specification's admission that such coating technology was "conventional" – to vary the ratio of drug to polymer to obtain a controlled release of drug over a period of two, three, or more weeks (i.e., "several weeks"). It was also well known that restenosis occurs over a period of several weeks, and therefore, it would have been reasonable for a person of ordinary skill in the art to develop a dosage form that would release drug from the stent over a period of several weeks. (*See, e.g.,* Morris patent, col. 6, ll. 57–60 (disclosing treatment with rapamycin for 14 days); *see also* Ex. 108 at BSC-SJA-1641 (In June 1994, long before the filing of the '662 patent, Dr. Lunn, another Cordis researcher, wrote "[d]esired features for [a stent] coating include . . . release in a time period of the order of 3 to 30 days").

Asserted Claim Limitation	Location in the Prior Art
2. The metallic stent according to claim 1 wherein said therapeutic agent is a macrocyclic lactone analog of rapamycin.	The Skotnicki '286 patent complements the disclosure of the Morris patent, and discloses ***"macrocyclic lactone analog[s] of rapamycin"*** (under either parties' proposed claim construction) useful for the treatment of hyperproliferative vascular disease and restenosis as required by claim 2.[2] (*See* Skotnicki '286 patent, col. 1, ll. 64–66; col. 2, ll. 1–50; col. 5, l. 57–col. 6, l. 2). In addition to disclosing rapamycin analogs in general, the Skotnicki '286 patent discloses at least one particular rapamycin derivative (a macrocyclic lactone analog) that demonstrates superior activity to rapamycin in the disclosed thymocyte proliferation assay. (*See id.* at col. 8, ll. 43–col. 9, l. 2).
3. The metallic stent according to claim 1 wherein said biocompatible polymeric carrier comprises a fluorinated polymer.	Under either parties' proposed claim constructions, the Berg patent also teaches the additional limitation of dependent claim 3 which additionally requires that: ***"said biocompatible polymeric carrier comprises a fluorinated polymer."*** Berg notes that "biostable polymers with a relatively low chronic tissue response [could be used] such as . . . polyvinylidene fluoride," a type of fluorinated polymer. (Berg patent at col. 4, l. 54–62).
4. The metallic according to claim 3 wherein said biocompatible polymeric carrier further comprises an acrylate-based polymer or copolymer.	Claim 4 of the '473 patent depends on claim 3 and further requires that: ***"said biocompatible polymeric carrier further comprises an acrylate-based polymer or copolymer."*** Applying either parties' proposed claim construction, Berg also discloses this limitation. More specifically, Berg describes the use of "acrylic polymers and copolymers," which are examples of acrylate-based polymers or copolymers. (Berg patent at col. 4, l. 59; *see also id.* at col. 7, ll. 49–52). Furthermore, Claim 6 of the

[2] In fact, the Skotnicki '286 patent references Morris's work concerning the effect of rapamycin on smooth muscle cell proliferation and intimal thickening following vascular injury. (Skotnicki '286 patent, col. 1, ll. 43–46).

Asserted Claim Limitation	Location in the Prior Art
	Berg patent expressly recites several polymer classes from among the larger group disclosed in the patent, including both acrylate homopolymers and copolymers. (*Id.* at col. 7, ll. 49–53).
5. A method of inhibiting neointimal proliferation in a coronary artery resulting from percutaneous transluminal coronary angioplasty comprising implanting a metallic stent according to any one of claims 1 to 4 in the lumen of said coronary artery.	Claim 5 of the '473 patent depends on claim 1, 2, 3, or 4, and requires the step of ***"implanting a metallic stent according to any one of claims 1 to 4 in the lumen of said coronary artery."*** The Berg patent teaches this additional limitation of claim 5. Specifically, the Berg patent discloses a polymer-drug coated stent designed for implantation into a coronary artery to inhibit neointimal proliferation following percutaneous transluminal coronary angioplasty: > This invention relates to intravascular stents for treatment of injuries to blood vessels and particularly to stents having a framework onto which a therapeutic substance or drug is applied. (Berg patent, col. 1, ll. 5–8 (emphasis added)). Further: > In operation, the stent made according to the present invention can deliver drugs to a body lumen by introducing the stent transluminally into a selected portion of the body lumen and radially expanding the stent into contact with the body lumen. The transluminal delivery can be accomplished by a catheter designed for the delivery of stents and the radial expansion can be accomplished by balloon expansion of the stent, self-expansion of the stent, or a combination of self-expansion and balloon expansion. (*Id.* at col. 3, ll. 1–9)

EXHIBIT C - CYPHER EMBODIES THE INVENTIONS OF THE PATENTS-IN-SUIT

U.S. Patent No. 7,217,286

'7286 Claim Element	Location of Claim Element In The Cypher® Stent
1. A device comprising	The Cypher® Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) is a device. *Cypher Instructions for Use* ("*Cypher® IFU*"), Ex. C1, at p. 3 (The Cypher® Stent "is a combination product comprised of two regulated components: a device (a stent system) and a drug product (a formulation of sirolimus in a polymer coating).").
a metallic stent,	The Cypher® Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) includes an electropolished stainless steel (316L) stent. *Cypher® IFU*, Ex. C1, at p. 3.
a biocompatible, nonabsorbable polymeric carrier,	The Cypher® Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) includes a biocompatible, nonerodible polymeric coating affixed to the intraluminal stent. *Cypher® IFU*, Ex. C1, at p. 4 ("The inactive ingredients in the Cypher Sirolimus-eluting Coronary Stent contain parylene C and the following two non-erodible polymers: polyethylene-co-vinyl acetate (PEVA) and poly n-butyl methacrylate (PBMA). A combination of the two polymers mixed with Sirolimus (67%/33%) makes up the basecoat formulation which is applied to a parylene C treated stent.").
and a therapeutic agent, wherein:	The basecoat formulation of the Cypher® Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) contains rapamycin. *Cypher® IFU*, Ex. C1, at p. 4.
said polymeric carrier comprises an acrylate-based polymer or copolymer, a fluorinated polymer, or a mixture thereof, and	The Cypher® IFU, Ex. C1, state at p. 4 that: "The inactive ingredients in the Cypher Sirolimus-eluting Coronary Stent contain parylene C and the following two non-erodible polymers: polyethylene-co-vinyl acetate (PEVA) and poly n-butyl methacrylate (PBMA). A combination of the two polymers mixed with Sirolimus (67%/33%) makes up the basecoat formulation which is applied to a parylene C treated stent." PBMA is an acrylate-based polymer or copolymer.
said therapeutic agent is rapamycin, or a macrocyclic lactone analog thereof,	The basecoat formulation of the Cypher® Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) contains rapamycin. *Cypher® IFU*, Ex. C1, at p. 4.

'7286 Claim Element	Location of Claim Element In The Cypher® Stent
and is present in an amount effective to inhibit neointimal proliferation.	Rapamycin is present on the Cypher® stent in an amount effective to inhibit neointimal proliferation. The Cypher® IFU describes the results of the SIRIUS trial of the Cypher stent as follows: "By follow up angiography at 8 months, there was significantly lower in-stent late loss (0.17 mm) and mean in-lesion % diameter stenosis was significantly reduced (23.6%)…Clinical outcomes through 12 months were consistent with the 9 month outcomes." *Cypher® IFU*, Ex. C1, at p. 12.
3. The device according to claim 1 that provides a controlled release of said therapeutic agent over a period of several weeks.	A portion of the sirolimus present in the Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) is released at six weeks following intraluminal implantation. *See* Kukreja *et al*, The Future of Drug Eluting Stents. *Pharmacol Res* 2008;57:171-180, Ex. C2, at pp. 171-172.
5. A method of inhibiting neointimal proliferation in a coronary artery resulting from percutaneous transluminal coronary angioplasty comprising implanting a device according to any one of claims 1 to 4 in the lumen of said coronary artery.	Implantation of the Cypher® Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) into the lumen of a human coronary artery inhibits neointimal proliferation in the artery resulting from percutaneous transluminal coronary angioplasty. The Cypher® IFU at p. 12 describe the results of the SIRIUS trial of the Cypher stent as follows: "By follow up angiography at 8 months, there was significantly lower in-stent late loss (0.17 mm) and mean in-lesion % diameter stenosis was significantly reduced (23.6%)…Clinical outcomes through 12 months were consistent with the 9 month outcomes." *Cypher® IFU*, Ex. C1, at p. 12.

U.S. Patent No. 7,229,473

'473 Claim Element	Location of Claim Element
1. A metallic stent having a coating applied thereto, wherein:	The Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) includes a stent having a coating applied to the stent. *Cypher Instructions for Use* ("*Cypher IFU*"), Ex. C1, at 3 (The Cypher Stent "is a combination product comprised of two regulated components: a device (a stent system) and a drug product (a formulation of sirolimus in a polymer coating).").
said coating comprises a mixture of a biocompatible polymeric carrier and a therapeutic agent;	The Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) includes a biocompatible polymeric carrier containing rapamycin. The Cypher Instructions for Use state at 4 that: "The inactive ingredients in the Cypher Sirolimus-eluting Coronary Stent contain parylene C and the following two non-erodible polymers: polyethylene-co-vinyl acetate (PEVA) and poly n-butyl methacrylate (PBMA). A combination of the two polymers mixed with Sirolimus (67%/33%) makes up the basecoat formulation which is applied to a parylene C treated stent." *Cypher IFU*, Ex. C1, at 4.
said polymeric carrier comprises at least one nonabsorbable polymer;	The Cypher Instructions for Use state at 4 that: "The inactive ingredients in the Cypher Sirolimus-eluting Coronary Stent contain parylene C and the following two non-erodible polymers: polyethylene-co-vinyl acetate (PEVA) and poly n-butyl methacrylate (PBMA). A combination of the two polymers mixed with Sirolimus (67%/33%) makes up the basecoat formulation which is applied to a parylene C treated stent." *Cypher IFU*, Ex. C1, at 4.
said therapeutic agent is rapamycin, or a macrocyclic lactone analog thereof,	The basecoat formulation of the Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) contains rapamycin. *Cypher IFU*, Ex. C1, at 4.
present in an amount effective to inhibit neointimal proliferation;	Rapamycin is present on the Cypher stent in an amount effective to inhibit neointimal proliferation. The Cypher Instructions for Use at 12 describe the results of the SIRIUS trial of the Cypher stent as follows: "By follow up angiography at 8 months, there was significantly lower in-stent late loss (0.17 mm) and mean in-lesion % diameter stenosis was significantly reduced (23.6%)...Clinical outcomes through 12 months were consistent with the 9 month outcomes." *Cypher IFU*, Ex. C1, at 12.

'473 Claim Element	Location of Claim Element
and said stent provides a controlled release of said therapeutic agent over a period of several weeks.	A portion of the sirolimus present in the Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) is released at thirty days following intraluminal implantation. *See also* Kukreja *et al*, The Future of Drug Eluting Stents, *Pharmacological Research* 2008;57:171-180, Ex. C2, at pp. 171-172.
5. A method of inhibiting neointimal proliferation in a coronary artery resulting from percutaneous transluminal coronary angioplasty comprising implanting a metallic stent according to any one of claims 1 to 4 in the lumen of said coronary artery.	Implantation of the Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) into the lumen of a human coronary artery inhibits neointimal proliferation in the artery resulting from percutaneous transluminal coronary angioplasty. The Cypher Instructions for Use at 12 describe the results of the SIRIUS trial of the Cypher stent as follows: "By follow up angiography at 8 months, there was significantly lower in-stent late loss (0.17 mm) and mean in-lesion % diameter stenosis was significantly reduced (23.6%)…Clinical outcomes through 12 months were consistent with the 9 month outcomes." *Cypher IFU*, Ex. C1, at 12.

U.S. Patent No. 7,223,286 Patent

'3286 Claim Element	Location of Claim Element
1. A stent having a coating applied thereto,	The Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) includes a stent having a coating applied to the stent. *Cypher Instructions for Use* ("*Cypher IFU*"), Ex. C1, at 3 (The Cypher Stent "is a combination product comprised of two regulated components: a device (a stent system) and a drug product (a formulation of sirolimus in a polymer coating).").
wherein said coating comprises a biocompatible polymer/drug mixture	The Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) includes a biocompatible polymeric carrier containing rapamycin. The Cypher Instructions for Use state at 4 that: "The inactive ingredients in the Cypher Sirolimus-eluting Coronary Stent contain parylene C and the following two non-erodible polymers: polyethylene-co-vinyl acetate (PEVA) and poly n-butyl methacrylate (PBMA). A combination of the two polymers mixed with Sirolimus (67%/33%) makes up the basecoat formulation which is applied to a parylene C treated stent." *Cypher IFU*, Ex. C1, at 4.
and said drug is rapamycin or a macrocyclic lactone analog thereof.	The basecoat formulation of the Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) contains rapamycin. *Cypher IFU*, Ex. C1, at 4.
2. A stent according to claim 1 comprising a generally thin walled cylinder containing a plurality of generally solid struts to which said coating is applied.	The Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) includes a stent made of "[e]lectropolished stainless steel (316L), laser-cut from seamless tubing in a sinusoidal pattern coated with a polymer and sirolimus mixture." *Cypher IFU*, Ex. C1, at 3. *See also* http://www.cypherstent.com/cypher-stent/specifications/pages/index.aspx, Ex. C3.
6. A stent according to claim 1 wherein the coating is spray-coated onto the stent.	The Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) includes a biocompatible polymeric carrier containing rapamycin that is spray-coated onto the stent.
7. A stent according to claim 1 wherein said rapamycin or macrocyclic lactone analog thereof is contained in the coating at a weight percentage of about 30%.	The Cypher Instructions for Use state at 4 that: "The inactive ingredients in the Cypher Sirolimus-eluting Coronary Stent contain parylene C and the following two non-erodible polymers: polyethylene-co-vinyl acetate (PEVA) and poly n-butyl methacrylate (PBMA). A combination of the two polymers mixed with Sirolimus (67%/33%) makes up the basecoat formulation which is applied to a parylene C treated stent." *Cypher IFU*, Ex. C1, at 4.

'3286 Claim Element	Location of Claim Element
9. A stent according to claim 1 wherein the coating comprises a nonabsorbable polymer.	The Cypher Instructions for Use state at 4 that: "The inactive ingredients in the Cypher Sirolimus-eluting Coronary Stent contain parylene C and the following two non-erodible polymers: polyethylene-co-vinyl acetate (PEVA) and poly n-butyl methacrylate (PBMA). A combination of the two polymers mixed with Sirolimus (67%/33%) makes up the basecoat formulation which is applied to a parylene C treated stent." *Cypher IFU*, Ex. C1, at 4.
10. A stent according to claim 1 wherein the coating comprises a lactone-based polyester; a lactone-based copolyester; a polyanhydride; a polyaminoacid; a polysaccharide; a polyphosphazene; a poly(ether-ester) copolymer; a polydimethylsiloxane; a poly(ethylene)vinylacetate; a poly(hydroxy)ethylmethylmethacrylate; an acrylate based polymer; an acrylate based copolymer; a polyvinyl pyrrolidone; a cellulose ester; a fluorinated polymer; or a blend thereof.	The Cypher Instructions for Use state at 4 that: "The inactive ingredients in the Cypher Sirolimus-eluting Coronary Stent contain parylene C and the following two non-erodible polymers: polyethylene-co-vinyl acetate (PEVA) and poly n-butyl methacrylate (PBMA). A combination of the two polymers mixed with Sirolimus (67%/33%) makes up the basecoat formulation which is applied to a parylene C treated stent." *Cypher IFU*, Ex. C1, at 4.
19. A stent according to claim 10 wherein the coating comprises a poly(ethylene)vinylacetate.	The Cypher Instructions for Use state at 4 that: "The inactive ingredients in the Cypher Sirolimus-eluting Coronary Stent contain parylene C and the following two non-erodible polymers: polyethylene-co-vinyl acetate (PEVA) and poly n-butyl methacrylate (PBMA). A combination of the two polymers mixed with Sirolimus (67%/33%) makes up the basecoat formulation which is applied to a parylene C treated stent." *Cypher IFU*, Ex. C1, at 4.
21. A stent according to claim 10 wherein the coating comprises an acrylate based polymer.	The Cypher Instructions for Use state at 4 that: "The inactive ingredients in the Cypher Sirolimus-eluting Coronary Stent contain parylene C and the following two non-erodible polymers: polyethylene-co-vinyl acetate (PEVA) and poly n-butyl methacrylate (PBMA). A combination of the two polymers mixed with Sirolimus (67%/33%) makes up the basecoat formulation which is applied to a parylene C treated stent." *Cypher IFU*, Ex. C1, at 4. PBMA is "an acrylate-based polymer or copolymer."
28. A stent according to any one of claims 1 to 26 that provides a controlled release of said rapamycin or macrocyclic lactone analog thereof over a period of several weeks.	A portion of the sirolimus present in the Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) is released at thirty days following intraluminal implantation. *See also* Kukreja *et al*, The Future of Drug Eluting Stents, *Pharmacological Research* 2008;57:171-180, Ex. C2, at pp. 171-172.

'3286 Claim Element	Location of Claim Element
30. A stent according to any one of claims 1 to 26 that releases said rapamycin or macrocyclic lactone analog thereof over a period of at least 14 days.	A portion of the sirolimus present in the Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) is released at thirty days following intraluminal implantation. *See also* Kukreja *et al*, The Future of Drug Eluting Stents, *Pharmacological Research* 2008;57:171-180, Ex. C2, at pp. 171-172.
32. A stent according to any one of claims 1 to 26 wherein said rapamycin or macrocyclic lactone analog thereof is present in a therapeutically beneficial amount to inhibit neointimal proliferation.	Rapamycin is present on the Cypher stent in a therapeutically beneficial amount to inhibit neointimal proliferation. The Cypher Instructions for Use at 12 describe the results of the SIRIUS trial of the Cypher stent as follows: "By follow up angiography at 8 months, there was significantly lower in-stent late loss (0.17 mm) and mean in-lesion % diameter stenosis was significantly reduced (23.6%)...Clinical outcomes through 12 months were consistent with the 9 month outcomes." *Cypher IFU*, Ex. C1, at 12.
40. A device comprising	The Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) is a device. *Cypher Instructions for Use* ("*Cypher IFU*"), Ex. C1, at 3 (The Cypher Stent "is a combination product comprised of two regulated components: a device (a stent system) and a drug product (a formulation of sirolimus in a polymer coating).").
a metallic stent,	The Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) includes an electropolished stainless steel (316L) stent. *Cypher IFU*, Ex. C1, at 3.
a biocompatible polymeric carrier and a drug,	The Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) includes a biocompatible polymeric carrier containing rapamycin. The Cypher Instructions for Use state at 4 that: "The inactive ingredients in the Cypher Sirolimus-eluting Coronary Stent contain parylene C and the following two non-erodible polymers: polyethylene-co-vinyl acetate (PEVA) and poly n-butyl methacrylate (PBMA). A combination of the two polymers mixed with Sirolimus (67%/33%) makes up the basecoat formulation which is applied to a parylene C treated stent." *Cypher IFU*, Ex. C1, at 4.
wherein said drug is rapamycin or a macrocyclic lactone analog thereof	The biocompatible polymer coating of the Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) contains rapamycin. *Cypher IFU*, Ex. C1, at 4.

'3286 Claim Element	Location of Claim Element
and is present in an amount effective to inhibit neointimal proliferation.	Rapamycin is present on the Cypher stent in an amount effective to inhibit neointimal proliferation. The Cypher Instructions for Use at 12 describe the results of the SIRIUS trial of the Cypher stent as follows: "By follow up angiography at 8 months, there was significantly lower in-stent late loss (0.17 mm) and mean in-lesion % diameter stenosis was significantly reduced (23.6%)…Clinical outcomes through 12 months were consistent with the 9 month outcomes." *Cypher IFU*, Ex. C1, at 12.
41. A device according to claim 40 wherein said polymeric carrier and drug are mixed together.	The Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) includes a biocompatible polymeric carrier containing rapamycin. The Cypher Instructions for Use state at 4 that: "The inactive ingredients in the Cypher Sirolimus-eluting Coronary Stent contain parylene C and the following two non-erodible polymers: polyethylene-co-vinyl acetate (PEVA) and poly n-butyl methacrylate (PBMA). A combination of the two polymers mixed with Sirolimus (67%/33%) makes up the basecoat formulation which is applied to a parylene C treated stent." *Cypher IFU*, Ex. C1, at 4.
44. A device according to claim 40 wherein said stent comprises a generally thin walled cylinder containing a plurality of generally solid struts to which said polymeric carrier and drug are applied.	The Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) includes a stent made of "[e]lectropolished stainless steel (316L), laser-cut from seamless tubing in a sinusoidal pattern coated with a polymer and sirolimus mixture." *Cypher IFU*, Ex. C1, at 3. *See also* http://www.cypherstent.com/cypher-stent/specifications/pages/index.aspx, Ex. C3.
48. A device according to claim 40 wherein the polymeric carrier and drug are spray-coated onto the stent.	The Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) includes a biocompatible polymeric carrier containing rapamycin that is spray-coated onto the stent.
49. A device according to claim 40 wherein the weight ratio of drug to polymeric carrier is about 3:7.	The Cypher Instructions for Use state at 4 that: "The inactive ingredients in the Cypher Sirolimus-eluting Coronary Stent contain parylene C and the following two non-erodible polymers: polyethylene-co-vinyl acetate (PEVA) and poly n-butyl methacrylate (PBMA). A combination of the two polymers mixed with Sirolimus (67%/33%) makes up the basecoat formulation which is applied to a parylene C treated stent." *Cypher IFU*, Ex. C1, at 4.
51. A device according to claim 40 wherein the polymeric carrier comprises a nonabsorbable polymer.	The Cypher Instructions for Use state at 4 that: "The inactive ingredients in the Cypher Sirolimus-eluting Coronary Stent contain parylene C and the following

'3286 Claim Element	Location of Claim Element
	two non-erodible polymers: polyethylene-co-vinyl acetate (PEVA) and poly n-butyl methacrylate (PBMA). A combination of the two polymers mixed with Sirolimus (67%/33%) makes up the basecoat formulation which is applied to a parylene C treated stent." *Cypher IFU*, Ex. C1, at 4.
52. A device according to claim 40 wherein the polymeric carrier comprises a lactone-based polyester; a lactone-based copolyester; a polyanhydride; a polyaminoacid; a polysaccharide; a polyphosphazene; a poly(ether-ester) copolymer; a polydimethylsiloxane; a poly(ethylene)vinylacetate; a poly(hydroxy)ethylmethylmethacrylate; an acrylate based polymer; an acrylate based copolymer; a polyvinyl pyrrolidone; a cellulose ester; a fluorinated polymer; or a blend thereof.	The Cypher Instructions for Use state at 4 that: "The inactive ingredients in the Cypher Sirolimus-eluting Coronary Stent contain parylene C and the following two non-erodible polymers: polyethylene-co-vinyl acetate (PEVA) and poly n-butyl methacrylate (PBMA). A combination of the two polymers mixed with Sirolimus (67%/33%) makes up the basecoat formulation which is applied to a parylene C treated stent." *Cypher IFU*, Ex. C1, at 4.
61. A device according to claim 52 wherein the polymeric carrier comprises a poly(ethylene)vinylacetate.	The Cypher Instructions for Use state at 4 that: "The inactive ingredients in the Cypher Sirolimus-eluting Coronary Stent contain parylene C and the following two non-erodible polymers: polyethylene-co-vinyl acetate (PEVA) and poly n-butyl methacrylate (PBMA). A combination of the two polymers mixed with Sirolimus (67%/33%) makes up the basecoat formulation which is applied to a parylene C treated stent." *Cypher IFU*, Ex. C1, at 4.
63. A device according to claim 52 wherein the polymeric carrier comprises an acrylate based polymer.	The Cypher Instructions for Use state at 4 that: "The inactive ingredients in the Cypher Sirolimus-eluting Coronary Stent contain parylene C and the following two non-erodible polymers: polyethylene-co-vinyl acetate (PEVA) and poly n-butyl methacrylate (PBMA). A combination of the two polymers mixed with Sirolimus (67%/33%) makes up the basecoat formulation which is applied to a parylene C treated stent." *Cypher IFU*, Ex. C1, at 4. PBMA is "an acrylate-based polymer or copolymer."
70. A device according to any one of claims 40 to 68 that provides a controlled release of said rapamycin or macrocyclic lactone analog thereof over a period of several weeks.	A portion of the sirolimus present in the Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) is released at thirty days following intraluminal implantation. *See also* Kukreja *et al*, The Future of Drug Eluting Stents, *Pharmacological Research* 2008;57:171-180, Ex. C2, at pp. 171-172.
74. A device according to any one of claims 40 to 68 that releases said drug over a period of at least 14 days.	A portion of the sirolimus present in the Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) is released at thirty days following intraluminal implantation. *See also* Kukreja

'3286 Claim Element	Location of Claim Element
	et al, The Future of Drug Eluting Stents, *Pharmacological Research* 2008;57:171-180, Ex. C2, at pp. 171-172.

U.S. Patent No. 7,223,286 Patent (As Amended in Ongoing Reexamination No. 95/001,097)

'3286 Claim Element	Location of Claim Element
1 [amended]. A stent having a coating applied thereto,	The Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) includes a stent having a coating applied to the stent. *Cypher Instructions for Use* ("*Cypher IFU*"), Ex. C1, at 3 (The Cypher Stent "is a combination product comprised of two regulated components: a device (a stent system) and a drug product (a formulation of sirolimus in a polymer coating).").
wherein said coating comprises a biocompatible polymer/drug mixture,	The Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) includes a biocompatible polymeric carrier containing rapamycin. The Cypher Instructions for Use state at 4 that: "The inactive ingredients in the Cypher Sirolimus-eluting Coronary Stent contain parylene C and the following two non-erodible polymers: polyethylene-co-vinyl acetate (PEVA) and poly n-butyl methacrylate (PBMA). A combination of the two polymers mixed with Sirolimus (67%/33%) makes up the basecoat formulation which is applied to a parylene C treated stent." *Cypher IFU*, Ex. C1, at 4.
said polymer is a nonabsorbable polymer,	The Cypher Instructions for Use state at 4 that: "The inactive ingredients in the Cypher Sirolimus-eluting Coronary Stent contain parylene C and the following two non-erodible polymers: polyethylene-co-vinyl acetate (PEVA) and poly n-butyl methacrylate (PBMA). A combination of the two polymers mixed with Sirolimus (67%/33%) makes up the basecoat formulation which is applied to a parylene C treated stent." *Cypher IFU*, Ex. C1, at 4.
and said drug is rapamycin or a macrocyclic lactone analog thereof.	The basecoat formulation of the Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) contains rapamycin. *Cypher IFU*, Ex. C1, at 4.
2. A stent according to claim 1 comprising a generally thin walled cylinder containing a plurality of generally solid struts to which said coating is applied.	The Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) includes a stent made of "[e]lectropolished stainless steel (316L), laser-cut from seamless tubing in a sinusoidal pattern coated with a polymer and sirolimus mixture." *Cypher IFU*, Ex. C1, at 3. *See also* http://www.cypherstent.com/cypher-stent/specifications/pages/index.aspx, Ex. C3.
6. A stent according to claim 1 wherein the coating is spray-coated onto the stent.	The Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) includes a biocompatible polymeric carrier containing rapamycin that is spray-coated onto the stent.

'3286 Claim Element	Location of Claim Element
7. A stent according to claim 1 wherein said rapamycin or macrocyclic lactone analog thereof is contained in the coating at a weight percentage of about 30%.	The Cypher Instructions for Use state at 4 that: "The inactive ingredients in the Cypher Sirolimus-eluting Coronary Stent contain parylene C and the following two non-erodible polymers: polyethylene-co-vinyl acetate (PEVA) and poly n-butyl methacrylate (PBMA). A combination of the two polymers mixed with Sirolimus (67%/33%) makes up the basecoat formulation which is applied to a parylene C treated stent." *Cypher IFU*, Ex. C1, at 4.
10 [amended]. A stent according to claim 1 wherein the coating comprises a polydimethylsiloxane; a poly(ethylene)vinylacetate; a poly(hydroxy)ethylmethylmethacrylate; an acrylate based polymer; an acrylate based copolymer; a polyvinyl pyrrolidone; a cellulose ester; a fluorinated polymer; or a blend thereof.	The Cypher Instructions for Use state at 4 that: "The inactive ingredients in the Cypher Sirolimus-eluting Coronary Stent contain parylene C and the following two non-erodible polymers: polyethylene-co-vinyl acetate (PEVA) and poly n-butyl methacrylate (PBMA). A combination of the two polymers mixed with Sirolimus (67%/33%) makes up the basecoat formulation which is applied to a parylene C treated stent." *Cypher IFU*, Ex. C1, at 4.
19. A stent according to claim 10 wherein the coating comprises a poly(ethylene)vinylacetate.	The Cypher Instructions for Use state at 4 that: "The inactive ingredients in the Cypher Sirolimus-eluting Coronary Stent contain parylene C and the following two non-erodible polymers: polyethylene-co-vinyl acetate (PEVA) and poly n-butyl methacrylate (PBMA). A combination of the two polymers mixed with Sirolimus (67%/33%) makes up the basecoat formulation which is applied to a parylene C treated stent." *Cypher IFU*, Ex. C1, at 4.
21. A stent according to claim 10 wherein the coating comprises an acrylate based polymer.	The Cypher Instructions for Use state at 4 that: "The inactive ingredients in the Cypher Sirolimus-eluting Coronary Stent contain parylene C and the following two non-erodible polymers: polyethylene-co-vinyl acetate (PEVA) and poly n-butyl methacrylate (PBMA). A combination of the two polymers mixed with Sirolimus (67%/33%) makes up the basecoat formulation which is applied to a parylene C treated stent." *Cypher IFU*, Ex. C1, at 4. PBMA is "an acrylate-based polymer or copolymer."
28 [amended]. A stent according to any one of claims 1 to 7, 10, or 18 to 26 that provides a controlled release of said rapamycin or macrocyclic lactone analog thereof over a period of several weeks.	A portion of the sirolimus present in the Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) is released at thirty days following intraluminal implantation. *See also* Kukreja *et al*, The Future of Drug Eluting Stents, *Pharmacological Research* 2008;57:171-180, Ex. C2, at pp. 171-172.
30. A stent according to any one of claims 1 to 26 that releases said rapamycin or macrocyclic lactone analog thereof over a period of at least 14 days.	A portion of the sirolimus present in the Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) is released at thirty days following intraluminal implantation. *See also* Kukreja

'3286 Claim Element	Location of Claim Element
	et al, The Future of Drug Eluting Stents, *Pharmacological Research* 2008;57:171-180, Ex. C2, at pp. 171-172.
32 [amended]. A stent according to any one of claims 1 to 7, 10 or 18 to 26 wherein said rapamycin or macrocyclic lactone analog thereof is present in a therapeutically beneficial amount to inhibit neointimal proliferation.	Rapamycin is present on the Cypher stent in a therapeutically beneficial amount to inhibit neointimal proliferation. The Cypher Instructions for Use at 12 describe the results of the SIRIUS trial of the Cypher stent as follows: "By follow up angiography at 8 months, there was significantly lower in-stent late loss (0.17 mm) and mean in-lesion % diameter stenosis was significantly reduced (23.6%)...Clinical outcomes through 12 months were consistent with the 9 month outcomes." *Cypher IFU*, Ex. C1, at 12.
40 [amended]. A device comprising	The Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) is a device. *Cypher Instructions for Use* ("*Cypher IFU*"), Ex. C1, at 3 (The Cypher Stent "is a combination product comprised of two regulated components: a device (a stent system) and a drug product (a formulation of sirolimus in a polymer coating).").
a metallic stent,	The Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) includes an electropolished stainless steel (316L) stent. *Cypher IFU*, Ex. C1, at 3.
a biocompatible polymeric carrier and a drug,	The Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) includes a biocompatible polymeric carrier containing rapamycin. The Cypher Instructions for Use state at 4 that: "The inactive ingredients in the Cypher Sirolimus-eluting Coronary Stent contain parylene C and the following two non-erodible polymers: polyethylene-co-vinyl acetate (PEVA) and poly n-butyl methacrylate (PBMA). A combination of the two polymers mixed with Sirolimus (67%/33%) makes up the basecoat formulation which is applied to a parylene C treated stent." *Cypher IFU*, Ex. C1, at 4.
wherein said polymer is a nonabsorbable polymer,	The Cypher Instructions for Use state at 4 that: "The inactive ingredients in the Cypher Sirolimus-eluting Coronary Stent contain parylene C and the following two non-erodible polymers: polyethylene-co-vinyl acetate (PEVA) and poly n-butyl methacrylate (PBMA). A combination of the two polymers mixed with Sirolimus (67%/33%) makes up the basecoat formulation which is applied to a parylene C treated stent." *Cypher IFU*, Ex. C1, at 4

'3286 Claim Element	Location of Claim Element
said drug is rapamycin or a macrocyclic lactone analog thereof	The biocompatible polymer coating of the Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) contains rapamycin. *Cypher IFU*, Ex. C1, at 4.
and is present in an amount effective to inhibit neointimal proliferation.	Rapamycin is present on the Cypher stent in an amount effective to inhibit neointimal proliferation. The Cypher Instructions for Use at 12 describe the results of the SIRIUS trial of the Cypher stent as follows: "By follow up angiography at 8 months, there was significantly lower in-stent late loss (0.17 mm) and mean in-lesion % diameter stenosis was significantly reduced (23.6%)...Clinical outcomes through 12 months were consistent with the 9 month outcomes." *Cypher IFU*, Ex. C1, at 12.
41. A device according to claim 40 wherein said polymeric carrier and drug are mixed together.	The Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) includes a biocompatible polymeric carrier containing rapamycin. The Cypher Instructions for Use state at 4 that: "The inactive ingredients in the Cypher Sirolimus-eluting Coronary Stent contain parylene C and the following two non-erodible polymers: polyethylene-co-vinyl acetate (PEVA) and poly n-butyl methacrylate (PBMA). A combination of the two polymers mixed with Sirolimus (67%/33%) makes up the basecoat formulation which is applied to a parylene C treated stent." *Cypher IFU*, Ex. C1, at 4.
44. A device according to claim 40 wherein said stent comprises a generally thin walled cylinder containing a plurality of generally solid struts to which said polymeric carrier and drug are applied.	The Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) includes a stent made of "[e]lectropolished stainless steel (316L), laser-cut from seamless tubing in a sinusoidal pattern coated with a polymer and sirolimus mixture." *Cypher IFU*, Ex. C1, at 3. *See also* http://www.cypherstent.com/cypher-stent/specifications/pages/index.aspx, Ex. C3.
48. A device according to claim 40 wherein the polymeric carrier and drug are spray-coated onto the stent.	The Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) includes a biocompatible polymeric carrier containing rapamycin that is spray-coated onto the stent.
49. A device according to claim 40 wherein the weight ratio of drug to polymeric carrier is about 3:7.	The Cypher Instructions for Use state at 4 that: "The inactive ingredients in the Cypher Sirolimus-eluting Coronary Stent contain parylene C and the following two non-erodible polymers: polyethylene-co-vinyl acetate (PEVA) and poly n-butyl methacrylate (PBMA). A combination of the two polymers mixed with Sirolimus (67%/33%) makes up the basecoat formulation which is applied to a parylene C treated

'3286 Claim Element	Location of Claim Element
	stent." *Cypher IFU*, Ex. C1, at 4.
52 [amended]. A device according to claim 40 wherein the polymeric carrier comprises a polydimethylsiloxane; a poly(ethylene)vinylacetate; a poly(hydroxy)ethylmethylmethacrylate; an acrylate based polymer; an acrylate based copolymer; a polyvinyl pyrrolidone; a cellulose ester; a fluorinated polymer; or a blend thereof.	The Cypher Instructions for Use state at 4 that: "The inactive ingredients in the Cypher Sirolimus-eluting Coronary Stent contain parylene C and the following two non-erodible polymers: polyethylene-co-vinyl acetate (PEVA) and poly n-butyl methacrylate (PBMA). A combination of the two polymers mixed with Sirolimus (67%/33%) makes up the basecoat formulation which is applied to a parylene C treated stent." *Cypher IFU*, Ex. C1, at 4.
61. A device according to claim 52 wherein the polymeric carrier comprises a poly(ethylene)vinylacetate.	The Cypher Instructions for Use state at 4 that: "The inactive ingredients in the Cypher Sirolimus-eluting Coronary Stent contain parylene C and the following two non-erodible polymers: polyethylene-co-vinyl acetate (PEVA) and poly n-butyl methacrylate (PBMA). A combination of the two polymers mixed with Sirolimus (67%/33%) makes up the basecoat formulation which is applied to a parylene C treated stent." *Cypher IFU*, Ex. C1, at 4.
63. A device according to claim 52 wherein the polymeric carrier comprises an acrylate based polymer.	The Cypher Instructions for Use state at 4 that: "The inactive ingredients in the Cypher Sirolimus-eluting Coronary Stent contain parylene C and the following two non-erodible polymers: polyethylene-co-vinyl acetate (PEVA) and poly n-butyl methacrylate (PBMA). A combination of the two polymers mixed with Sirolimus (67%/33%) makes up the basecoat formulation which is applied to a parylene C treated stent." *Cypher IFU*, Ex. C1, at 4. PBMA is "an acrylate-based polymer or copolymer."
70 [amended]. A device according to any one of claims 40 to 49, 52, or 60 to 68 that provides a controlled release of said rapamycin or macrocyclic lactone analog thereof over a period of several weeks.	A portion of the sirolimus present in the Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) is released at thirty days following intraluminal implantation. *See also* Kukreja *et al*, The Future of Drug Eluting Stents, *Pharmacological Research* 2008;57:171-180, Ex. C2, at pp. 171-172.
74 [amended]. A device according to any one of claims 40 to 49, 52, or 60 to 68 that releases said drug over a period of at least 14 days.	A portion of the sirolimus present in the Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) is released at thirty days following intraluminal implantation. *See also* Kukreja *et al*, The Future of Drug Eluting Stents, *Pharmacological Research* 2008;57:171-180, Ex. C2, at pp. 171-172.

U.S. Patent No. 7,300,662

'662 Patent Claim Element	Location of Claim Element
1. A drug delivery device comprising:	The Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) is a drug delivery device. *Cypher IFU*, Ex. C1, at 3 (The Cypher Stent "is a combination product comprised of two regulated components: a device (a stent system) and a drug product (a formulation of sirolimus in a polymer coating).").
an intraluminal stent;	The Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) includes an electropolished stainless steel (316L) stent. *Cypher IFU*, Ex. C1, at 3.
a biocompatible, nonerodible polymeric coating affixed to the intraluminal stent;	The Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) includes a biocompatible, nonerodible polymeric coating affixed to the intraluminal stent. The Cypher Instructions for Use state at 4 that: "The inactive ingredients in the Cypher Sirolimus-eluting Coronary Stent contain parylene C and the following two non-erodible polymers: polyethylene-co-vinyl acetate (PEVA) and poly n-butyl methacrylate (PBMA). A combination of the two polymers mixed with sirolimus (67%/33%) makes up the basecoat formulation which is applied to a parylene C treated stent." *Cypher IFU*, Ex. C1, at 4.
and from about 64 μg to about 197 μg of rapamycin or a macrocyclic triene analog thereof that binds FKBP12 incorporated into the polymeric coating,	The basecoat formulation of the Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) contains dosages of rapamycin that fall within the claimed range. *Cypher IFU*, Ex. C1, at 4. In cells, rapamycin "binds to the immunophilin, FK Binding Protein-12 (FKBP-12)." *Cypher IFU*, Ex. C1, at 6.
wherein said device provides an in-stent late loss in diameter at 12 months following implantation in a human of less than about 0.5 mm, as measured by quantitative coronary angiography.	The Cypher Instructions for Use at 12 describe the results of the SIRIUS trial of the Cypher stent as follows: "By follow up angiography at 8 months, there was significantly lower in-stent late loss (0.17 mm)...Clinical outcomes through 12 months were consistent with the 9 month outcomes." *Cypher IFU*, Ex. C1, at 12. *See also* Expert Report of Joseph Wiedermann at ¶ 85, Expert Report of Garrett Fitzmaurice at ¶¶ 61-65.

'662 Patent Claim Element	Location of Claim Element
2. A drug delivery device according to claim 1 that provides an in-stent late loss in diameter at 12 months following implantation in a human of less than about 0.3 mm, as measured by quantitative coronary angiography	The Cypher Instructions for Use at 12 describe the results of the SIRIUS trial of the Cypher stent as follows: "By follow up angiography at 8 months, there was significantly lower in-stent late loss (0.17 mm)…Clinical outcomes through 12 months were consistent with the 9 month outcomes." *Cypher IFU*, Ex. C1, at 12. *See also* Expert Report of Joseph Wiedermann at ¶ 85, Expert Report of Garrett Fitzmaurice at ¶¶ 61-66.
3. A drug delivery device according to claim 1 or 2 that provides an in-stent diameter stenosis at 12 months following implantation in a human of less than about 22%, as measured by quantitative coronary angiography.	The Cypher Instructions for Use at 12 describe the results of the SIRIUS trial of the Cypher stent as follows: "By follow up angiography at 8 months, there was significantly lower in-stent late loss (0.17 mm) and mean in-lesion % diameter stenosis was significantly reduced (23.6%)…Clinical outcomes through 12 months were consistent with the 9 month outcomes." *Cypher IFU*, Ex. C1, at 12. *See also* Expert Report of Joseph Wiedermann at ¶ 85, Expert Report of Garrett Fitzmaurice at ¶¶ 61-64, 67-68.
5. A drug delivery device comprising:	The Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) is a drug delivery device. *Cypher IFU*, Ex. C1, at 3 (The Cypher Stent "is a combination product comprised of two regulated components: a device (a stent system) and a drug product (a formulation of sirolimus in a polymer coating).").
an intraluminal stent;	The Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) includes an electropolished stainless steel (316L) stent. *Cypher IFU*, Ex. C1, at 3.
a biocompatible, nonerodible polymeric coating affixed to the intraluminal stent;	The Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) includes a biocompatible, nonerodible polymeric coating affixed to the intraluminal stent. The Cypher Instructions for Use state at 4 that: "The inactive ingredients in the Cypher Sirolimus-eluting Coronary Stent contain parylene C and the following two non-erodible polymers: polyethylene-co-vinyl acetate (PEVA) and poly n-butyl methacrylate (PBMA). A combination of the two polymers mixed with sirolimus (67%/33%) makes up the basecoat formulation which is applied to a parylene C treated stent." *Cypher IFU*, Ex. C1, at 4.

'662 Patent Claim Element	Location of Claim Element
and from about 64 μg to about 197 μg of rapamycin or a macrocyclic triene analog thereof that binds FKBP12 incorporated into the polymeric coating,	The basecoat formulation of the Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) contains dosages of rapamycin that fall within the claimed range. *Cypher IFU*, Ex. C1, at 4. In cells, rapamycin "binds to the immunophilin, FK Binding Protein-12 (FKBP-12)." *Cypher IFU*, Ex. C1, at 6.
wherein said device provides a mean in-stent late loss in diameter in a human population at 12 months following implantation of less than about 0.5 mm, as measured by quantitative coronary angiography.	The Cypher Instructions for Use at 12 describe the results of the SIRIUS trial of the Cypher stent as follows: "By follow up angiography at 8 months, there was significantly lower in-stent late loss (0.17 mm)…Clinical outcomes through 12 months were consistent with the 9 month outcomes." *Cypher IFU*, Ex. C1, at 12. *See also* Expert Report of Joseph Wiedermann at ¶ 85, Expert Report of Garrett Fitzmaurice at ¶¶ 61-65.
6. A drug delivery device according to claim 5 that provides a mean in-stent late loss in diameter in a human population at 12 months following implantation of less than about 0.3 mm, as measured by quantitative coronary angiography	The Cypher Instructions for Use at 12 describe the results of the SIRIUS trial of the Cypher stent as follows: "By follow up angiography at 8 months, there was significantly lower in-stent late loss (0.17 mm)…Clinical outcomes through 12 months were consistent with the 9 month outcomes." *Cypher IFU*, Ex. C1, at 12. *See also* Expert Report of Joseph Wiedermann at ¶ 85, Expert Report of Garrett Fitzmaurice at ¶¶ 61-66.
7. A drug delivery device according to claim 5 or 6 that provides a mean in-stent diameter stenosis in a human population at 12 months following implantation of less than about 22%, as measured by quantitative coronary angiography.	The Cypher Instructions for Use at 12 describe the results of the SIRIUS trial of the Cypher stent as follows: "By follow up angiography at 8 months, there was significantly lower in-stent late loss (0.17 mm) and mean in-lesion % diameter stenosis was significantly reduced (23.6%)…Clinical outcomes through 12 months were consistent with the 9 month outcomes." *Cypher IFU*, Ex. C1, at 12. *See also* Expert Report of Joseph Wiedermann at ¶ 85, Expert Report of Garrett Fitzmaurice at ¶¶ 61-64, 67-68.
9. A method of inhibiting neointimal proliferation in a human coronary artery resulting from percutaneous transluminal coronary angioplasty comprising implanting in the lumen of said coronary artery a drug delivery device comprising:	Implantation of the Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) into the lumen of a human coronary artery inhibits neointimal proliferation in the artery resulting from percutaneous transluminal coronary angioplasty. The Cypher Instructions for Use at 12 describe the results of the SIRIUS trial of the Cypher stent as follows: "By follow up angiography at 8 months, there was significantly lower in-stent late loss (0.17 mm) and mean in-

'662 Patent Claim Element	Location of Claim Element
	lesion % diameter stenosis was significantly reduced (23.6%)...Clinical outcomes through 12 months were consistent with the 9 month outcomes." *Cypher IFU*, Ex. C1, at 12.
an intraluminal stent;	The Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) includes an electropolished stainless steel (316L) stent. *Cypher IFU*, Ex. C1, at 3.
a biocompatible, nonerodible polymeric coating affixed to the intraluminal stent;	The Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) includes a biocompatible, nonerodible polymeric coating affixed to the intraluminal stent. The Cypher Instructions for Use state at 4 that: "The inactive ingredients in the Cypher Sirolimus-eluting Coronary Stent contain parylene C and the following two non-erodible polymers: polyethylene-co-vinyl acetate (PEVA) and poly n-butyl methacrylate (PBMA). A combination of the two polymers mixed with sirolimus (67%/33%) makes up the basecoat formulation which is applied to a parylene C treated stent." *Cypher IFU*, Ex. C1, at 4.
and from about 64 μg to about 197 μg of rapamycin or a macrocyclic triene analog thereof that binds FKBP12 incorporated into the polymeric coating,	The basecoat formulation of the Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) contains dosages of rapamycin that fall within the claimed range. *Cypher IFU*, Ex. C1, at 4. In cells, rapamycin "binds to the immunophilin, FK Binding Protein-12 (FKBP-12)." *Cypher IFU*, Ex. C1, at 6.
wherein said method provides an in-stent late loss in diameter at 12 months following implantation of less than about 0.5 mm, as measured by quantitative coronary angiography.	The Cypher Instructions for Use at 12 describe the results of the SIRIUS trial of the Cypher stent as follows: "By follow up angiography at 8 months, there was significantly lower in-stent late loss (0.17 mm)...Clinical outcomes through 12 months were consistent with the 9 month outcomes." *Cypher IFU*, Ex. C1, at 12. *See also* Expert Report of Joseph Wiedermann at ¶ 85, Expert Report of Garrett Fitzmaurice at ¶¶ 61-65.
10. A method according to claim 9 that provides an in-stent late loss in diameter at 12 months following implantation of less than about 0.3 mm, as measured by quantitative coronary angiography.	The Cypher Instructions for Use at 12 describe the results of the SIRIUS trial of the Cypher stent as follows: "By follow up angiography at 8 months, there was significantly lower in-stent late loss (0.17 mm)...Clinical outcomes through 12 months were consistent with the 9 month outcomes." *Cypher IFU*, Ex. C1, at 12. *See also* Expert Report of

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	Joseph Wiedermann at ¶ 85, Expert Report of Garrett Fitzmaurice at ¶¶ 61-66.
11. A method according to claim 9 or 10 that provides an in-stent diameter stenosis at 12 months following implantation of less than about 22%, as measured by quantitative coronary angiography.	The Cypher Instructions for Use at 12 describe the results of the SIRIUS trial of the Cypher stent as follows: "By follow up angiography at 8 months, there was significantly lower in-stent late loss (0.17 mm) and mean in-lesion % diameter stenosis was significantly reduced (23.6%)…Clinical outcomes through 12 months were consistent with the 9 month outcomes." *Cypher IFU*, Ex. C1, at 12. *See also* Expert Report of Joseph Wiedermann at ¶ 85, Expert Report of Garrett Fitzmaurice at ¶¶ 61-64, 67-68.
13. A method of inhibiting neointimal proliferation in a coronary artery resulting from percutaneous transluminal coronary angioplasty comprising implanting in the lumen of said coronary artery a drug delivery device comprising:	Implantation of the Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) into the lumen of a human coronary artery inhibits neointimal proliferation in the artery resulting from percutaneous transluminal coronary angioplasty. The Cypher Instructions for Use at 12 describe the results of the SIRIUS trial of the Cypher stent as follows: "By follow up angiography at 8 months, there was significantly lower in-stent late loss (0.17 mm) and mean in-lesion % diameter stenosis was significantly reduced (23.6%)…Clinical outcomes through 12 months were consistent with the 9 month outcomes." *Cypher IFU*, Ex. C1, at 12.
an intraluminal stent;	The Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) includes an electropolished stainless steel (316L) stent. *Cypher IFU*, Ex. C1, at 3.
a biocompatible, nonerodible polymeric coating affixed to the intraluminal stent;	The Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) includes a biocompatible, nonerodible polymeric coating affixed to the intraluminal stent. The Cypher Instructions for Use state at 4 that: "The inactive ingredients in the Cypher Sirolimus-eluting Coronary Stent contain parylene C and the following two non-erodible polymers: polyethylene-co-vinyl acetate (PEVA) and poly n-butyl methacrylate (PBMA). A combination of the two polymers mixed with sirolimus (67%/33%) makes up the basecoat formulation which is applied to a parylene C treated stent." *Cypher IFU*, Ex. C1, at 4.

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and from about 64 μg to about 197 μg of rapamycin or a macrocyclic triene analog thereof that binds FKBP12 incorporated into the polymeric coating,	The basecoat formulation of the Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) contains dosages of rapamycin that fall within the claimed range. *Cypher IFU*, Ex. C1, at 4. In cells, rapamycin "binds to the immunophilin, FK Binding Protein-12 (FKBP-12)." *Cypher IFU*, Ex. C1, at 6.
wherein said method provides a mean in-stent late loss in diameter in a human population at 12 months following implantation of less than about 0.5 mm, as measured by quantitative coronary angiography.	The Cypher Instructions for Use at 12 describe the results of the SIRIUS trial of the Cypher stent as follows: "By follow up angiography at 8 months, there was significantly lower in-stent late loss (0.17 mm)…Clinical outcomes through 12 months were consistent with the 9 month outcomes." *Cypher IFU*, Ex. C1, at 12. *See also* Expert Report of Joseph Wiedermann at ¶ 85, Expert Report of Garrett Fitzmaurice at ¶¶ 61-65.
14. A method according to claim 13 that provides a mean in-stent late loss in diameter in a human population at 12 months following implantation of less than about 0.3 mm, as measured by quantitative coronary angiography.	The Cypher Instructions for Use at 12 describe the results of the SIRIUS trial of the Cypher stent as follows: "By follow up angiography at 8 months, there was significantly lower in-stent late loss (0.17 mm)…Clinical outcomes through 12 months were consistent with the 9 month outcomes." *Cypher IFU*, Ex. C1, at 12. *See also* Expert Report of Joseph Wiedermann at ¶ 85, Expert Report of Garrett Fitzmaurice at ¶¶ 61-66.
15. A method according to claim 13 or 14 that provides a mean in-stent diameter stenosis in a human population at 12 months following implantation of less than about 22%, as measured by quantitative coronary angiography.	The Cypher Instructions for Use at 12 describe the results of the SIRIUS trial of the Cypher stent as follows: "By follow up angiography at 8 months, there was significantly lower in-stent late loss (0.17 mm) and mean in-lesion % diameter stenosis was significantly reduced (23.6%)…Clinical outcomes through 12 months were consistent with the 9 month outcomes." *Cypher IFU*, Ex. C1, at 12. *See also* Expert Report of Joseph Wiedermann at ¶ 85, Expert Report of Garrett Fitzmaurice at ¶¶ 61-64, 67-68.
17. The drug delivery device according to any one of claims 1, 2, 4 or 5 wherein said rapamycin or macrocyclic triene analog thereof is incorporated into the polymeric coating at a dose of from about 64 μg to about 125 μg.	The basecoat formulation of the Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) contains dosages of rapamycin that fall within the claimed range. *Cypher IFU*, Ex. C1, at 4.
18. The drug delivery device according to any one of claims 1, 2, 4 or 5 that releases a portion of said dose of rapamycin or a macrocyclic triene analog thereof at about six weeks following intraluminal implantation.	A portion of the sirolimus present in the Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) is released at six weeks following intraluminal implantation. *See*

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	Balakrishnan *et al*, Intravascular drug release kinetcics dictate arterial drug deposition, retention, and distribution, *Journal of Controlled Release* 2007;123:100-108 ("Balakrishnan et al. (2007)"), Ex. C4, at pp. 103.
19. The drug delivery device according to any one of claims 1, 2, 4 or 5 wherein said rapamycin or macrocyclic triene analog thereof is incorporated into the polymeric coating at a dose of from about 2 μg to about 30 μg per millimeter of stent length.	The basecoat formulation of the Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) contains between 8.1 μg and 10.3 μg of rapamycin per millimeter of stent length depending on the size of the stent. *Cypher IFU*, Ex. C1, at 4.
20. The drug delivery device according to claim 19 wherein said rapamycin or macrocyclic triene analog thereof is incorporated into the polymeric coating at a dose of from about 3 μg to about 13 μg per millimeter of stent length.	The basecoat formulation of the Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) contains between 8.1 μg and 10.3 μg of rapamycin per millimeter of stent length depending on the size of the stent. *Cypher IFU*, Ex. C1, at 4.
21. The drug delivery device according to claim 19 that releases a portion of said dose of rapamycin or a macrocyclic triene analog thereof at about six weeks following intraluminal implantation.	A portion of the sirolimus present in the Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) is released at six weeks following intraluminal implantation. *See* Balakrishnan et al. (2007), Ex. C4, at pp. 103.
22. The method according to any one of claims 9, 10, 13 or 14, wherein said rapamycin or macrocyclic triene analog thereof is incorporated into the polymeric coating at a dose of from about 64 μg to about 125 μg.	The basecoat formulation of the Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) contains dosages of rapamycin that fall within the claimed range. *Cypher IFU*, Ex. C1, at 4.
23. The method according to any one of claims 9, 10, 13 or 14, wherein said rapamycin or macrocyclic triene analog thereof is incorporated into the polymeric coating at a dose of from about 2 μg to about 30 μg per millimeter of stent length.	The basecoat formulation of the Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) contains between 8.1 μg and 10.3 μg of rapamycin per millimeter of stent length depending on the size of the stent. *Cypher IFU*, Ex. C1, at 4.
24. The method according to any one of claims 9, 10, 13 or 14, wherein said rapamycin or macrocyclic triene analog thereof is incorporated into the polymeric coating at a dose of from about 3 μg to about 13 μg per millimeter of stent length.	The basecoat formulation of the Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) contains between 8.1 μg and 10.3 μg of rapamycin per millimeter of stent length depending on the size of the stent. *Cypher IFU*, Ex. C1, at 4.
25. The method according to any one of claims 9, 10, 13 or 14, wherein said drug delivery device releases a portion of said dose of rapamycin or a macrocyclic triene analog thereof at about six weeks following	A portion of the sirolimus present in the Cypher Sirolimus-eluting Coronary Stent Delivery System (on Raptor and RaptorRail) is released at six weeks following intraluminal implantation. *See*

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intraluminal implantation.	Balakrishnan et al. (2007), Ex. C4, at pp. 103.